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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,260	12/12/2005	Seiichi Toki	3240-7449US	1642

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EXAMINER	
ZHENG, LI	
ART UNIT	**PAPER NUMBER**
1638	
MAIL DATE	**DELIVERY MODE**
06/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,260	TOKI ET AL.	
	Examiner	Art Unit	
	Li Zheng	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-11* is/are pending in the application.

4a) Of the above claim(s) *2,5,6,9 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,4,7,8 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment to claims 3 filed on 3/13/2007 is acknowledged.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 3-4, 7-8 and 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for removing transposons flanked by FRT sequence, does not reasonably provide enablement for transposing a transposon that is not flanked by FRT sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are drawn to a method for transposing a transposon that does not have a transposes, wherein the method comprises the steps of : using Agrobacterium to introduce an FLP-encoding DNA into a transformed plant that comprises the transposon having no transposase, and transiently expressing the transpose and the resulting plant/reproductive material produced by the method.

The specification proposes a method to remove a hygromycin resistance gene cassette flanked by FRT sequence as a result of the FLP action (page 9, paragraph [0043]).

However, it is not known in the art that FLP site-specific recombinase is able to recognize any transposon without being flanked by FRT sequences or its variants. The specification also fails to provide any guidance on how to practice the invention to removing those transposons without FRT sequences. Undue experimentation would be required for a person skilled in the art to practice the invention for removing any transposons.See *Genentech Inc. v. Novo Nordisk,* A/S (CA FC) 42 USPQ2d 1001 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Claim Rejections - 35 USC § 102

4. Claims 4 and 8 remain rejected under 35 U.S.C. 102(b) as being anticipated by Weld et al., for the reasons of record stated in the Office action mailed November 14, 2006. Applicants traverse in the paper filed March 13,

2007. Applicants' arguments have been fully considered but were not found partial persuasive.

Applicant argue that Weld et al. do not teach FLP expressly or inherently (response, page 4, 3rd paragraph). However, claims 4 and 8 are drawn to transformed plant/ reproductive material with the transposon being transposed. The resulting transformed plant/reproductive material does not have to retain the construct expressing FLP due to the limitation of "transiently expressing the transposase" in claim 3. Therefore claims 4 and 8 read on any transformed plant and reproductive material thereof with the transposon being transposed.

Claim Rejections - 35 USC § 103

5. Claim 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weld et al., for the reasons of record stated in the Office action mailed November 14, 2006. Applicants traverse in the paper filed March 13, 2007. Applicants' arguments have been fully considered but were not found partial persuasive.

Applicants argue that dependent claims are nonobvious if the independent claim from which they depend is not obvious (page 5, last paragraph). However, as discussed above, the independent claim 4 is anticipated by Weld et al.

6. Claims 3-4, 7-8 an 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gleave et al. (1999, Plant Molecular Biology 40:223-235) and Applicants' own admitted prior art.

The claims are drawn to a method for transposing a transposon that does not have a transposes, wherein the method comprises the steps of : using Agrobacterium to introduce an FLP-encoding DNA into a transformed plant that comprises the transposon having no transposase, and transiently expressing the transposase; or the resulting plant/reproductive material produced by the method.

Gleave et al. teach a method to generate a marker free tobacco plant by removing the codA and nptII cassettes due to a transient expression of cre recombinase (abstract; also Figure 1 and page 229, 3rd paragraph of the right column), wherein the DNA encoding the recombinase was introduced via Agrobacterium. Gleave et al. also teach T1 progeny of resulting plant is generated (the paragraph bridging pages 229-230). Given the broadest interpretation of the transposon without transposase, the codA and nptII cassettes of Gleave et al. is considered to meet the limitation.

Gleave et al. do not teach the use of FLP site-specific recombinase.

Applicants' own admitted prior art teaches that it was known in the prior art that sequences flanked by the FRT sites could be excised by transiently expressing an FLP gene in plant protoplasts (Specification , page 3, paragraph [0008]).

It would have been obvious for a person with ordinary skill in the art to modify the method of Gleave et al. by replacing the cre/lox system with the FLP/FRT system, resulting in the instant invention with reasonable expectation of success. One would have been motivated to make such a modification given the similar mode of action of the two site-specific recombination systems and the teaching of Applicants' own admitted state of the prior art that transiently expressing an FLP gene could excise the sequence flanked by the FRT sites.

Summary

Claims 3-4, 7-8 an 11 are rejected.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory

action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ASHWIN D. MEHTA, PH.D.
PRIMARY EXAMINER